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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,460	03/16/2004	Gregory J. Kellogg	95,1408-VVV	3207

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

MAIL DATE	DELIVERY MODE
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06/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,460

Applicant(s)

KELLOGG ET AL.

Examiner

Nathan A. Bowers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>092006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 20 September 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, cited non-patent literature publications have not been evaluated because 1 copy of each publication was not provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "the sample chamber" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is understood that the claim should read "wherein the sample input port further comprises a sample chamber."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 2, 4 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (US 6030581).

With respect to claim 1, Virtanen discloses a centripetally-motivated microsystem platform comprising a rotatable platform comprising a substrate (Figure 1:10) having a surface comprising a multiplicity of microfluidics structures (Figure 1:11) embedded in the surface of the platform. Each microfluidics structure comprises a sample input port (Figure 2:14) fluidly connected to a chamber (Figure 2:15, 17, 19) in thermal contact with a temperature control element. A sample outlet port in the form of a waste chamber (Figure 2:20) is additionally provided. This is described in column 4, line 17 to column 5, line 63 and in column 11, line 42 to column 12, line 3. Virtanen teaches that the temperature control element changes the temperature of a fluid in the chamber at a temperature greater than ambient temperature. The rotation of the platform causes heated or cooled fluids to move throughout the microsystem, and thereby affect the temperature across the entire substrate.

With respect to claim 2, Virtanen discloses the apparatus in claim 1, wherein the temperature control element is a resistive heater. Column 11, line 42 to column 12, line 3 states that heating is achieved electrically using electrodes. Resistive heating is well known in the art as an effective electrical heating technique.

With respect to claim 4, Virtanen discloses the apparatus in claim 1, wherein a temperature sensing element is in thermal contact with the chamber and the temperature control element. Column 11, line 42 to column 12, line 3 indicate that a thermostat is utilized to regulate temperature within the system.

With respect to claims 12 and 13, Virtanen discloses the apparatus in claim 1, wherein the temperature of a fluid in the chamber can be changed at a rate sufficient for performing PCR. This is described in column 11, line 42 to column 12, line 3.

With respect to claim 14, Virtanen discloses the apparatus in claim 1, wherein the microsystem platform is a circular disk. This is apparent from the Figures.

With respect to claim 15, Virtanen discloses the apparatus in claim 1, wherein a sample chamber (Figure 1:15) and a sample input port (Figure 1:14) are provided. This is described in column 4, line 17 to column 5, line 63.

2) Claims 1, 12, 13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham (US 5639428).

With respect to claim 1, Cottingham discloses a centripetally-motivated microsystem platform comprising a substrate (Figure 3:34) having a surface comprising a multiplicity of microfluidic structures (Figure 4:36) embedded in the surface of the

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platform. Each microfluidic structure comprises a sample input port (Figure 4:66) fluidly connected to a chamber (Figure 3:51, 54) in thermal contact with a temperature control element (Figure 3:48, 52) and a sample outlet port (Figure 4:60). This is described in column 6, line 48 to column 8, line 15. Column 13, line 20 to column 14, line 13 indicate that the temperature control element changes the temperature of the fluid in the chamber according to the requirements of a specified reaction. The rotation of the platform causes heated or cooled fluids to move throughout the microsystems, and thereby affect the temperature across the entire substrate.

With respect to claims 12 and 13, Cottingham discloses the apparatus in claim 1, wherein the temperature of a fluid in the chamber can be changed at a rate sufficient for performing PCR. This is described in column 13, lines 20-45.

With respect to claim 15, Cottingham discloses the apparatus in claim 1, wherein a sample chamber (Figure 3:64) and a sample input port (Figure 4:60) are provided.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (US 6030581) as applied to claim 1, and further in view of Wilding (US 6660517).

Virtanen discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejections above. Although Virtanen does disclose the use of resistive heating elements and temperature sensors, Virtanen does not specifically disclose the use of Peltier heaters and thermistors.

Wilding discloses a microfluidic substrate comprising an inlet port in fluid communication with a plurality of reaction chambers and an outlet port. Column 16, line 27 to column 18, line 12 indicates that the apparatus comprises a plurality of

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resistive heaters and temperature sensors capable of carrying out PCR. Wilding specifically discloses the use of Peltier heaters and thermistors.

Virtanen and Wilding are analogous art because they are from the same field of endeavor regarding thermal cycling apparatuses.

At the time of the invention, it would have been obvious to ensure that the heating elements and temperature sensing elements disclosed by Virtanen were Peltier heaters and thermistor sensors. As evidenced by Wilding, these devices are well known in the art, effective in PCR applications, and capable of being incorporated within a microfluidic device.

4) Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (US 6030581) as applied to claim 1, and further in view of Pourahmadi (US 20050194316), Richards (US 6296809) and Haff (US 5827480).

Virtanen discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly disclose the use of an electric platen comprising a substrate bearing a multiplicity of temperature control elements.

Pourahmadi discloses a microfluidic chip comprising a substrate (Figure 16:165) that includes a sample inlet port fluidly connected to a plurality of processing chambers. Heating elements are provided to cycle reagents through a plurality of different temperatures. This is described in paragraphs [0200]-[0204]. Pourahmadi indicates that the substrate is in communication with a circuit board (Figure 16:167) comprising a

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multiplicity of temperature control elements (Figure 16:169, 193) in the form of resistive heaters. The elements are connected to a power source through leads.

Virtanen and Pourahmadi are analogous art because they are from the same field of endeavor regarding microsystems designed for biochemical analysis.

At the time of the invention, it would have been obvious to position the temperature control elements disclosed by Virtanen upon a circuit board in communication with the substrate. In paragraphs [0056]-[0059], Pourahmadi teaches that a circuit board is easily connected to an electronic controller, thereby allowing for effective regulation of the associated temperature control elements. The use of circuit boards bearing resistive heaters designed to carry out nucleic acid amplification reactions is considered to be well known in the art.

The combination of Virtanen and Pourahmadi still differs from Applicant's claimed invention because Virtanen and Pourahmadi do not disclose the use of a slip ring.

Richards discloses a rotating carousel capable of accommodating a plurality of reaction slides. Heaters are provided on the carousel and are used to control the temperature at each slide. Column 3, lines 57-67, column 6, lines 44-65 and column 13, lines 19-53 state that a slip ring is used to connect electronics located on the rotating carousel with a power source.

Haff discloses a rotatable heat exchange assembly (Figure 24:300) that comprises a plurality of temperature control elements (Figure 24:302-304). Rotation of the assembly allows a fluid sample to be exposed to each heating element during PCR.

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This is described in column 22, line 35 to column 25, line 4. Haff discloses that a slip ring is used to electrically connect the heaters to a power source.

Virtanen, Richards and Haff are analogous art because they are from the same field of endeavor regarding rotating substrates designed for biochemical analysis.

At the time of the invention, it would have been obvious to utilize a slip ring in the construction of the apparatus of Virtanen and Pourahmadi. As evidenced by Richards and Haff, slip rings are well known in the art as effective means by which resistive heaters on a rotating substrate are connected to a power source. Pourahmadi fails to disclose a slip ring because his circuit board and substrate are not designed to rotate. However, in modifying the rotating microfluidic assembly of Virtanen, it would have been obvious to utilize a slip ring to connect the temperature control elements to a power source.

5) Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (US 6030581) in view of Pourahmadi (US 20050194316), Richards (US 6296809) and Haff (US 5827480) as applied to claim 6, and further in view of Petersen (US 6391541).

Virtanen, Pourahmadi, Richards and Haff disclose the apparatus set forth in claim 6 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose the use of a brass plate in contact with the temperature control elements and a heat sink.

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Petersen discloses a reaction vessel (Figure 22:40) capable of accommodating a sample fluid. Resistive heating elements (Figure 24:206) are positioned along the walls of the reaction vessel in order to control the temperature of the fluid. Brass plates (Figure 23:190) are also positioned along the walls of the reaction vessel in order to facilitate heat transfer. A heat sink is also in contact with the plates. This is described in column 22, line 6 to column 23, line 30.

Virtanen, Pourahmadi, Richards, Haff and Petersen are analogous art because they are from the same field of endeavor regarding microsystems designed for biochemical analysis.

At the time of the invention, it would have been obvious to ensure that the reaction areas disclosed in the apparatus of Virtanen were in communication with heating elements, a metal contact plate, and a heat sink. Petersen teaches that this arrangement is effective in rapidly heating and cooling a sample fluid during PCR, thereby increasing the efficiency of the operation. Brass is known in the art as a good conductor of heat, and therefore is capable of regulating the temperature within a reaction chamber with the aid of heating and cooling means.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 17-19, 27 and 28 of U.S. Patent No. 6706519. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are generic to those of U.S. Patent No. 6706519. U.S. Patent No. 6706519 discloses the use of a rotatable platform comprising a substrate, a sample input port, chambers, a temperature control element, and a sample outlet port. U.S. Patent No. 6706519 also includes other limitations specifically directed to the use of a plurality of additional chambers and reagents.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Zanzucchi (US 5863708) reference discloses the state of the art regarding rotatable microsystems.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NAB



GLADYS J. CORCORAN
SUPERVISORY PATENT EXAMINER